Image 16538

Atty. Dkt. No. 033236-0115

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Steve Qi et al.

Title: CONTROLLED RELEASE FORMULATION COMPRISING GNRH-II

Appl. No.: 09/857,115

Filing Date: 6/1/2001

Examiner: MOHAMED, Abdel A.

Art Unit: 1653

REQUIREMENT FOR RESTRICTION AND ELECTION OF SPECIES TRANSMITTAL

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Transmitted herewith is an amendment in the above-identified application.

[X] Applicants hereby petition for an extension of time under 37 C.F.R. §1.136(a) for the total number of months checked below:

[X]	Extension for response filed within the first month:	$110.00	$110.00
[ ]	Extension for response filed within the second month:	$420.00	$0.00
[ ]	Extension for response filed within the third month:	$950.00	$0.00
		EXTENSION FEE TOTAL:	$110.00
		TOTAL FEE:	$110.00

[X] A check in the amount of $110.00 is enclosed.

[X] The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any

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overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date 23 December 2003 By S. G. Bent

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REQUIREMENT FOR RESTRICTION AND ELECTION OF SPECIES

Mail Stop NON-FEE AMENDMENT
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the restriction requirement set forth in the Office Action, dated October 23, 2003, applicants hereby provisionally elect Group I, claims 1-5 for examination, with traverse. In addition, applicants provisionally elect SEQ ID NO:6, with traverse. Finally, applicants hereby provisionally elect Species a, drawn to polymers listed in claims 3, 4, or 9, for examination.

The Examiner has required restriction between claims 1-5 (Group I), drawn to a pharmaceutical formulation comprising peptides with biodegradable polymers (product), and claims 6-13 (Group II), drawn to a method for treatment of disorders by administering the pharmaceutical formulation of Group I and use of such formulation thereof (process). In addition, the Examiner has required election of a single sequence for examination. Finally, the Examiner has required election of a species between Species a, relating to polymers listed in claims 3, 4, or 9, and Species b, relating to disorders listed in claims 10, 11, or 13. Restriction

was required because the Examiner asserts that the sequences described as SEQ ID NO:7 and SEQ ID NO:6 encompass peptides having different structures and that searching more than a single sequence per application creates an undue burden on the Office. Applicants respectfully traverse the restriction requirement.

The Commissioner may require restriction if the national stage application relates to more than a single general inventive concept (PCT Rule 13). According to the relevant PTO rule, "a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn" to, *inter alia*, a "product and process of use of said product." 37 CFR § 1.475(b)(2). In the present case, although the claimed subject matter may be classified in different classes, it forms a single general inventive concept. Specifically, the claims are drawn to a product, i.e., a pharmaceutical formulation comprising peptides with biodegradable polymers, and a process of using said product, i.e., treatment of disorders by administering the product. Accordingly, the Group I and Group II claims are "so linked as to form a single general inventive concept" (*id.*), fulfilling the requirement for unity of invention.

In addition, according to the PCT Handbook, section 33.35, a designated Office should not raise an objection as to a lack of unity when the International Searching and/or Preliminary Examining Authority has found that the claims comply with the requirement for unity of invention. Applicants note that the International Examination Report for the above-referenced application does not formally raise a lack of unity objection. Thus, applicants respectfully request that the restriction requirement be withdrawn and the Examiner examine each of claims 1-5 and claims 6-13 presently pending in this application.

With respect the restriction requirement among the sequences, applicants respectfully submit that there is a commonality between the SEQ ID NO: 7 and SEQ ID NO:6. SEQ ID NO:7 is pyro Glu-His-Trp-Ser-Xaa^1-Gly-Xaa^2-Xaa^3-Pro-Gly-NH_2, wherein Xaa^1 is His or Tyr, Xaa^2 is Trp or Leu, and Xaa^3 is Tyr or Arg. SEQ ID NO:6, which is pyro Glu-His-Trp-Ser-His-Gly-Trp-Tyr-Pro-Gly-NH_2, is merely SEQ ID NO:7, where Xaa^1 is His, Xaa^2 is Trp, and Xaa^3 is Tyr. Therefore, SEQ ID NO:6 is a sub-combination of SEQ ID NO:7. Thus, applicants submit that

these sequences should be examined together and request that the Examiner withdraw the restriction requirement.

Applicants reserve the right to file one or more divisional applications to cover the subject matter not elected for prosecution in this case. Meanwhile, the Examiner is invited to contact the undersigned, should there be any questions about this case.

Respectfully submitted,

Date 23 December 2007 By S. A. Bent

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